DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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WARNING LETTER

April 9, 2002

Larry Melton
Owner
Ashland Drug
Highway 5
P.O. Box 126
Ashland, MS 38603

Dear Mr. Melton:

This letter concerns **Nicotine Lollipops,** which are currently marketed by your firm as shown on your Internet sites www.nicotinelollipops.com and www.storesonline.com. According to information on these sites, your product consists of Nicotine combined with a natural sweetener, and flavorings in a sugar-free base, and is available in ½ mg., 1 mg., 2 mg., or 4 mg. dosages. Based on this product's description on your Internet sites, the **Nicotine Lollipops** are intended as an aid for smoking cessation or to reduce nicotine addiction.

The intended uses noted above are conveyed through claims on your Internet sites. These include statements such as "...Nicotine Lollipops can help you quit smoking... Nicotine Lollipops are a convenient, tasty way to replace your cigarette habit and help you quit smoking...Nicotine Lollipops helps smokers quit their tobacco habit by suppressing symptoms of nicotine withdrawal...If you are a regular smoker who smokes one or more packs of regular cigarettes, we have 4mg Nicotine Lollipops for you. For lighter smokers (less than one pack per day, lites or ultra-lites) we have 2mg strength. As you reduce your craving for nicotine we can customize the nicotine strength down to 1mg and 1/2mg as needed...Not only do Nicotine Lollipops provide you with the nicotine your body craves, they also deal with the hand to mouth fixation that is a big part of the cigarette habit. You control the amount of nicotine depending on your needs. During stressful times your need for nicotine increases...Nicotine Lollipops let you provide your body with just the amount of nicotine it needs to satisfy a craving. Once your craving is satisfied, return the lollipop to its handy, resealable, bag and save it for the next time you need it... Who are Nicotine Lollipops made for? People wanting to quit smoking and/or

reduce nicotine addition. And for smokers – in non-smoking environment. Each Nicotine Lollipop will last a regular smoker through 4 cigarette breaks. They come packaged in a ziplock bag that can be used for saving lollipops between uses. Nicotine Lollipops are custom compounded for you at our state-of-the-art pharmacy..."

Based on the intended uses established by your Internet sites, your **Nicotine Lollipops**, ½ mg., 1 mg., 2 mg., and 4 mg., are "drugs" as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The **Nicotine Lollipops** do not qualify for the exemptions from sections 505 and 502(f)(1) provided under section 503A of the Act since, according to your Internet site, you do not appear to require prescriptions to be presented to compound the product. Among other requirements, to qualify for the statutory exemptions provided by Section 503A, drugs must be compounded based on the receipt of valid prescription orders from licensed practitioners. You must also use only those substances that conform to Section 503A(b)(1)(A). If you are using Nicotine salicylate, please note that it is not a component of an FDA approved drug, is not listed in a United States Pharmacopoeia (USP) or National Formulary (NF) monograph, and was not nominated for inclusion in a list of bulk drug substances for compounding. Although nicotine and nicotine polacrilex are components of FDA approved drugs and are listed in the USP/NF, nicotine salicylate is not. Therefore, nicotine salicylate is not permitted for use in compounding.

Your **Nicotine Lollipops**, ½ mg., 1 mg., 2 mg., and 4 mg., are also subject to Title 21 of the Code of Federal Regulations (CFR) section 310.544. Under that regulation, they are "new drugs" as defined by section 201(p) of the Act. Under Section 505(a) of the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. We note that your **Nicotine Lollipops** drug products are not the subject of FDA-approved NDAs and, therefore, they may not be marketed in the United States. The continued distribution of these products without approved NDAs violates Section 505 of the Act.

In addition, your **Nicotine Lollipops**, ½ mg., 1 mg., 2 mg., and 4 mg., are misbranded within the meaning of section 502(o) of the Act in that they are manufactured in an establishment not duly registered under section 510 of the Act and they have not been listed as required by section 510(j) of the Act. They also may be misbranded under section 502(f)(1) of the Act on the grounds that their labeling fails to bear adequate directions for the uses for which they are being offered and they would not be exempt from this requirement under 21 CFR section 201.115 since they are unapproved new drugs. These products may also be misbranded under Section 502(f)(2) of the Act on the grounds that their labeling fails to bear such adequate warnings against use by children where their use may be dangerous to health.

This letter is not intended to be an all-inclusive review of your Internet sites and the products marketed by your firm and is not intended to be an all-inclusive list of the

deficiencies of you and your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with Federal laws and regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We request that you reply in writing within fifteen (15) days of your receipt of this letter stating the action your firm will take to discontinue marketing of these drug products. Your response should be directed to Melvin F. Szymanski, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, Metropark North I, Room 200, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

David J. Horowitz, Esq.
Acting Director
Office of Compliance
Center for Drug Evaluation and Research

cc:[ ]